REMARKS/ARGUMENTS

Telephonic Interview with the Examiner

Applicants thank Examiner Murphy for the telephonic interview with Eugenia Garrett-Wackowski and Jennifer Wahlsten on Monday, December 20, 2004. The rejections of the pending official action were discussed. Applicants offered proposed amendments to the claims.

To address the rejection under Section 112, first paragraph, enablement requirement, Applicants suggested incorporating into Claim 33 a definition as provided on page 13, lines 12-16 of the specification for "CAR-compromised mammal." The Examiner agreed with this suggestion.

To address the rejection under Section 112, second paragraph, for the recitation of "modulate" in Claim 1, Applicants proposed splitting Claim 1 into two independent claims: a first claim directed to a method for identifying an agonist of a CAR-mediated intermolecular interaction, and a second claim directed to a method for identifying an antagonist of a CAR-mediated intermolecular interaction. The Examiner agreed with this proposal.

To address the rejection under Section 112, second paragraph, for the recitation of "CAR-compromised mammal," Applicants suggested incorporating into Claim 33 a definition as provided on page 13, lines 12-16 of the specification for "CAR-compromised mammal." The Examiner agreed with this suggestion.

To address the rejection under Section 112, second paragraph, that Claim 1 omitted essential steps, Applicants offered that the particular molecules for which their interaction is to be measured and how the interaction is measured are not essential to practicing the method of Claim 1. Instead, dependent Claims 6-9 and 60 represent the many different ways the method of Claim 1 can be successfully practiced. The Examiner agreed.

Status of the Claims

Upon entry of the present amendment, Claims 1-2 and 33 are amended, Claim 3 is canceled and new Claims 60-67 are added.

Claim 1 is amended to set forth a method of identifying a therapeutic agent that comprises an agonist of a CAR-mediated intermolecular interaction, wherein the test mammal is compared to a control mammal in which the therapeutic agent is not administered. Support for identifying an agonist is found, for example, on page 31, lines 1-10 and page 52, lines 1-10.

Claim 2 is amended to recite additional candidate agonists of a CAR-mediated intermolecular interaction. Support is found, for example, on page 30, and on page 52, lines 1-10.

Claim 33 is amended to set forth a definition of a CAR-compromised mammal. Support is found, for example, on page 13, lines 12-16.

New Claim 60 sets forth the method of Claim 1, wherein the CAR-mediated intermolecular interaction comprises CAR binding to a ligand for CAR. Support is found, for example, on page 4, lines 19-21, Section A1 on direct and displacement assays on pages 17-22, page 31, lines 1-6, and in Example 8, on page 51, line 20 through page 52, line 9.

New independent Claim 61 sets forth a method of identifying a therapeutic agent that comprises an antagonist of a CAR-mediated intermolecular interaction, wherein the test mammal is compared to a control mammal in which the therapeutic agent is not administered. "Inverse antagonist" is defined on page 12, lines 20-25 to refer to a compound that acts on the same target as that of an agonist, but produces an opposite effect of the agonist. "Antagonist" is defined on page 12, lines 26-29 to refer to a compound that opposes the actions of an agonist. Support for identifying an antagonist is found, for example, on page 31, lines 1-10, page 3, lines 20-32, page 6, lines 8-19, page 12, lines 20-29, and page 33, lines 15-22.

New Claim 62 sets forth a Markush group of candidate antagonists. Support is found, for example on page 3, lines 20-32, page 6, lines 8-19, and on page 12, lines 20-29.

New Claims 63-66 find support in originally filed claims 6-9.

New Claim 67 sets forth the method of Claim 61, wherein the CAR-mediated intermolecular interaction comprises CAR binding to a ligand for CAR. Support is found, for example, on page 4, lines 19-21, Section A1 on direct and displacement assays on pages 17-22, and on page 31, lines 1-6.

Rejection under 35 U.S.C. § 112, first paragraph, enablement requirement

Claims 33-41 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner objects to recitation of the phrase "CAR-compromised mammal."

In accordance with the suggestion of the Examiner, Applicants have amended Claim 33 to incorporate a definition for "CAR-compromised mammal" provided on page 13, lines 12-16 of the specification. The Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 112, second paragraph

A. Recitation of "modulate"

Claims 1-9 are rejected under 35 U.S.C. § 112, second paragraph, for reciting that "said compounds can modulate."

As discussed in the telephonic interview of December 20, 2004, Applicants have amended independent Claim 1 to set forth a method for identifying a therapeutic agent that comprises an agonist of a CAR-mediated intermolecular interaction. New independent Claim 61 sets forth a method for identifying a therapeutic agent that comprises an antagonist of a CAR-mediated intermolecular interaction. Neither claim recites "modulate." In Claim 1, the cholesterol indicator is decreased, and in Claim 61, the cholesterol indicator is increased.

Because the metes and the bounds of Claims 1 and 61 are clearly set forth, the Examiner is respectfully requested to withdraw this rejection.

B. Recitation of "CAR-compromised mammal"

Claims 33-41 are rejected under 35 U.S.C. § 112, second paragraph, for reciting "CAR-compromised mammal."

This rejection is rendered moot by incorporating a definition for "CAR-compromised mammal" as provided on page 13, lines 12-16 of the specification.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

C. Failure to recite allegedly essential steps

Claims 1-9 are rejected under 35 U.S.C. § 112, second paragraph, for failing to recite allegedly essential steps in the screening step.

This rejection is respectfully traversed, because the molecules for which their interaction is to be measured and how this interaction is to be measured are not essential to successfully carry out the method of independent Claim 1. First, dependent Claims 6-9 and new Claim 60 set forth several specific approaches to carrying out the screening step. Second, the specification teaches that the screening step can be carried out successfully using different approaches (*see, for example*, page 4, lines 19-21 and page 31, lines 1-6). Finally, the specification further demonstrates how different screening approaches can be carried out successfully (*see*, Examples 8-9 on page 51, line 19 through page 53, line 4).

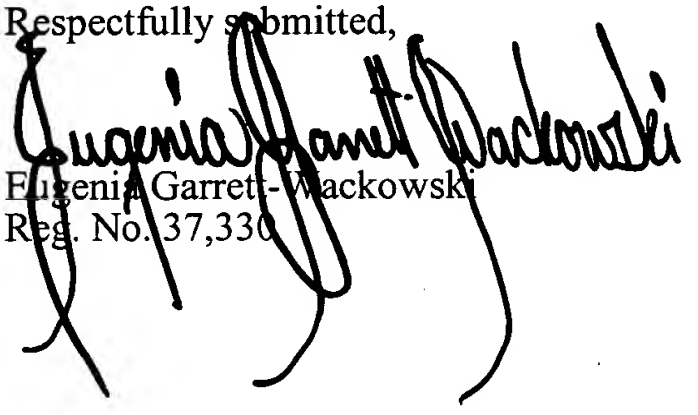
In view of the foregoing, Applicants respectfully assert that essential steps for carrying out the methods for identifying a therapeutic agent set forth in independent Claims 1 and 61 are recited in the claims. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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